REMARKS

Claims 1-90, 96, 106-129, 181-182, 199-202, and 206-213 have been canceled, without prejudice or disclaimer. Claims 93 and 130-131 have been amended to incorporate the limitations of the claims from which they previously depended. Claims 130, 185, and 198 have been amended to recite grass group 2/3 allergen; support for this amendment can be found throughout the specification and, in particular, on page 28, lines 19-23 and page 34, lines 15-16. New claims 217-244 have been added. Support for these new claims can be found throughout the specification and in the claims as originally filed. Additionally, support for new claims 239 and 240 can be found in the specification as filed, for example, on page 26, lines 19-21; support for new claims 241 and 242 can be found in the specification as filed, for example, on page 26, line 22 – page 27, line 2; support for new claims 243 and 244 can be found in the specification as filed, for example, on page 17, lines 13-20; page 18, lines 14-19; page 18, lines 24 page 19, line 4; page 27, lines 3-19; page 28, lines 16-18; and page 34, lines 15-22. No new matter has been added by way of these claim amendments or new claims.

Upon entry of the present amendment, claims 97-104, 130-131, 193-198, 203-205, 214-244 will be pending and under examination and claims 91-95, 105, 132-180, and 183-192 will be withdrawn.

Rejections under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1, 6-21, 25, 37, 40, 42-71, 81, 83-85, 90-95, 97-105, 109-112, and 114-216 as being obvious over WO 00/61117 ("the '117 application") in view of Roser (U.S. Patent No. 5,762,961), Cho et al., Remington's, Cleland, Pradalier and Hordijk et al. The Examiner contends that the '117 application discloses a fast-dispersing molded dosage form comprising a matrix carrier for active agents, such as antihistamines and proteins, containing fish gelatin and other components such as mannitol which dissolves in less than 60 seconds (particularly 2 to 8 seconds) in the mouth. The Examiner then contends that the difference between the '117 application and the claimed invention is that the '117 application does not expressly disclose that

the active ingredient is grass pollen allergen where the loss of the allergen content in the dosage form is less than 50% of the initial allergen content after being held for 3 months at 25°C and 60% relative humidity, and the loss of allergen content from the solid dosage form is less than about 0.5 μg allergen extract or less than about 0.05 μg major allergen when subjected to a friability test.

The Examiner cites Remington's for disclosing the importance of storage stability and stability of the active ingredient and solid dosage formulation when the product is subject to handling and transport, humidity and increased temperatures. Cho and Cleland are cited for disclosing that the addition of sugars, such as mannitol, prevent or inhibit protein degradation and aggregation in the presence of moisture and increased temperature. Pradalier and Hordijk are cited for disclosing that oral administration of grass pollen allergens is effective in immunotherapy of grass pollen allergies. Roser is cited for disclosing rapidly soluble tablets, such as molded tables that contain trehalose and can contain binders such as starch, gelatin, sugars, gum, wherein the active ingredients include antihistamines, proteins, peptides and antigens. The Examiner concludes that the ordinary skilled artisan would have been motivated to combine and/or modify the prior art with the expectation that mannitol would inhibit degradation over time of the grass pollen allergen extract in the presence of increased temperatures and humidity, that preparation of solid dosage forms which are stable to shaking and tumbling would inhibit loss of grass pollen allergen extract during handling and transportation and that oral administration of grass pollen allergen extract would be effective for immunotherapy of grass pollen allergies.

Without conceding the Examiner's position, claims 1, 6-21, 25, 37, 40, 42-71, 81, 83-85, 90, 109-112, and 114-129 have been canceled by way of this amendment. Each of the currently pending claims under examination requires kits or multiple dose sets, wherein each solid dosage form or dose contains "**the same amount of allergen**" (claims 97-104, 130-131)or "**essentially the same effective dose of at least one major allergen**" (claims 193-199, 203-205 and 214-216) (emphasis added). None of the art cited by the Examiner in this rejection discloses or suggests multiple dose sets or kits having the same amount or dose of allergen in each dosage unit or essentially the same effective dose of at least one major allergen. In contrast, the Pradalier and Hordijk references teach

the opposite of same dose administration and, instead, teach what was the state of the art at the time of the invention; specifically these references disclose the sequential administration of **an incremental increase in dosage**, followed by a single maintenance dose (see, *e.g.*, Methods section of Abstract of Pradalier and Methods and Results section of Summary of Hordijk). Additionally, it is noted that the Examiner cites Pradalier and Hordijk for disclosing that oral administration of grass pollen allergens is effective in immunotherapy of grass pollen allergies. However, it is respectfully pointed out that the updosing and maintenance doses of allergen of Hordijk are not administered via a solid dosage form, as is called for by the subsisting claims, but by sublingual drops. Additionally, the updosing allergen doses of Pradalier are not administered via a solid dosage form, as called for by the instant claims, but rather by sublingual drops. None of the references cited by the Examiner in this rejection discloses or suggests a multiple dose set or kit in which each dose contains the same amount or dose of allergen or essentially the same effective dose of at least one major allergen. Accordingly, the presently pending claims cannot be obvious in view of these references and withdrawal of this ground for rejection is respectfully requested.

Additionally, the Examiner cites a total of seven references to piece together this obviousness rejection. The Examiner has shown no motivation or reason for combining these seven references. It is improper for the Examiner to combine references in the absence of a motivation or reason to combine them. The mere fact that the teachings of seven references must be combined to reject the present claims under the guise of obviousness is evidence that such claims are not obvious. It is the Applicants, not the prior art, that teach a kit containing allergen dosage forms as called for here. The Examiner is synthesizing reasons to combine the cited prior based upon the teachings of the present application. This type of hindsight reconstruction is improper and has been condemned by the courts. *See In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention"); *In re Fitch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992); *See also Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569 (Fed. Cir. 1991) ("We do not 'pick and choose among the individual elements of assorted prior art references to recreate the claimed invention,' but rather, we look for 'some teaching or suggestion in the references to support

their use in the particular claimed combination.'"). Furthermore, as discussed above, even if combined, these references fail to suggest a required element of the claims (**the same amount of allergen**" (claims 97-104, 130-131)or "**essentially the same effective dose of at least one major allergen**" (claims 193-199, 203-205 and 214-216)). Accordingly, the presently pending claims cannot be obvious in view of these references and withdrawal of this ground for rejection is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

By _____
S. Peter Ludwig
Registration No.: 25,351
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant